



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

CR

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,686	10/01/2001	Michael Austin	S63.2-10142	1843

490 7590 12/26/2002

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

JIMENEZ, MARC QUEMUEL

ART UNIT

PAPER NUMBER

3726

DATE MAILED: 12/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/966,686	AUSTIN, MICHAEL
	Examiner Marc Jimenez	Art Unit 3726

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 December 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 27-41,44 and 45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 27-41,44 and 45 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 02 December 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____ .

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . 6) Other: _____ .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. **Claims 27, 28, 33-36, and 41** are rejected under 35 U.S.C. 102(e) as being anticipated by Morales (5,893,852).

Morales teaches a method of reducing a stent in cross-section comprising the steps of: providing a plurality of closely spaced wedge-shaped movable (col. 8, lines 61-63) dies 30 having a length and a stent contacting portion 62, the dies 30 disposed about a circle 66 (see fig. 5A) and forming an aperture, placing a stent 10 within the aperture (see fig. 2) so as to surround the stent 10 with the dies 30, and moving (col. 8, lines 61) the dies 30 such that the dies 30 exert a uniform force to the stent 10 along the length of the stent contacting portion 62 of the dies 30 so as to reduce the size of the aperture.

Note that the stent 10 is disposed about a medical balloon 14, the medical balloon 14 disposed about a catheter 11, the stent 10 is deformed, and the dies 30 are moved cooperatively inward during the moving step.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 29, 37, and 44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (5,893,852) in view of Langstedt (5,935,476).

Morales teaches the invention cited above with the exception of the dies being cooled below ambient temperature.

Langstedt teaches dies being cooled below ambient temperature (col. 2, lines 57-65).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the invention of Morales with the dies being cooled below ambient temperature, in light of the teachings of Langstedt, in order to facilitate rapid cooling (col. 1, line 16 of Langstedt).

5. **Claims 30 and 38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (5,893,852) in view of Langstedt as applied to **Claims 29 and 37** above, and further in view of Humphrey et al. (5,992,000).

Morales/Langstedt teach the invention cited above with the exception of the stent being made of nitinol.

Humphrey et al. teach a stent made of nitinol (col. 9, lines 32-34).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the invention of Morales/Langstedt with a stent made of nitinol, in light of the teachings of Humphrey et al., in order to provide a stent material that is durable.

6. **Claims 31, 32, 39, and 40** are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morales (5,893,852).

Although Morales teaches that the number of wedge-shaped dies **30** can be more than four teeth (col. 9, line 24), this teaching suggest that the number of wedge-shaped dies covers 8 or 16 dies since a number more than 4 covers 8 and 16, Morales does not specifically teach having either 8 wedge-shaped dies or 16 wedge-shaped dies.

It would have been obvious to one of ordinary skill in the art, at the time of the invention, that the particular number of wedge-shaped dies is clearly a matter of design choice, wherein no significant problems are solved by using either 8 or 16 wedge-shaped dies, versus using 4 or more wedge shaped dies as taught by Morales. It appears that using 4 or more wedge-shaped dies as taught by Morales would work equally as well as using the claimed 8 or 16 wedge-shaped dies.

7. **Claim 45** is rejected under 35 U.S.C. 103(a) as being unpatentable over Morales in view of Langstedt as applied to **Claim 37** above, and further in view of Hess et al. (5,545,210).

Morales/Langstedt teach the invention cited above with the exception of the stent being cooled so that it is in the martensitic state.

Hess et al. teach cooling a stent to martensitic state (col. 3, line 49).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the invention of Morales/Langstedt with cooling the stent to martensitic state, in light of the teachings of Hess et al., in order to utilize the shape memory properties of the stent.

Response to Arguments

8. Applicant's arguments filed 12/20/02 have been fully considered but they are not persuasive.
9. Applicant argues that the dies of Morales are not closely spaced dies, however, as shown in fig. 2, the dies **30** are adjacent to each other and are therefore closely spaced. Applicant further argues that there is spacing between the dies, however, the claims do not preclude spacing between the dies because the claims recite “closely **spaced**”. Closely spaced does not necessarily mean the dies are touching.
10. Applicant argues that the aperture defined by Morales is defined by the unmovable portions of the collar in combination of the dies. It is noted, however, that the dies **30** define an aperture that surrounds the stent **10**. As the dies move radially toward the stent, the dies crimp the stent, therefore, the aperture reduces in size.
11. Applicant argues that Morales does not suggest the desirability of having more than four dies, however, Morales clearly teaches in col. 9, lines 23-24, “..., there may be more or fewer than four teeth as described above.”.
12. Applicant argues that there is no motivation to combine Morales and Charzewki, however, Charzewki teaches cooling of the dies in order to facilitate cooling of the dies.

Applicant argues that the intended function of the crimper would be destroyed by applying the heating element as taught in Charzewski, however, the heating element is not relied upon, rather it is the teaching of cooling the dies. In response to applicant's argument that Charzewski is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Charzewski solves the same problem of cooling dies.

13. Applicant argues that while Humphrey et al. does teach the known use of a stent made of Nitinol, Humphrey et al. does not teach or suggest the missing elements. It is unclear which missing elements applicant is referring to in this argument. Furthermore, Humphrey et al. was only relied upon for teaching a stent made of Nitonol, not any other element.

Contact Information

14. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, should be directed to the group clerical personnel. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information. M.P.E.P. 203.08. The Group clerical receptionist number is (703) 308-1148.

If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers or other general questions should be directed to Tech Center 3700 Customer

Service at (703) 306-5648, or fax (703) 872-9301 or by email to
CustomerService3700@uspto.gov.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Jimenez whose telephone number is **703-306-5965**. The examiner can normally be reached on **Monday-Thursday and the second Friday of the bi-week, between 9am-6pm.**

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Greg Vidovich can be reached on 703-308-1513. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Other helpful telephone numbers are listed for applicant's benefit.

Allowed Files & Publication	(703) 308-6789 or (888) 786-0101
Assignment Branch	(703) 308-9723
Certificates of Correction	(703) 305-8309
Drawing Corrections/Draftsman	(703) 305-8404/8335
Petitions/Special Programs	(703) 305-9285
Terminal Disclaimers	(703) 305-8408
PCT Help Desk	(703) 305-3257

If the information desired is not provided above, or a number has been changed, please call the general information help line below.

Information Help line	1-800-786-9199
Internet PTO-Home Page	http://www.uspto.gov/

MJ
MJ
December 17, 2002

Greg Vidovich
GREGORY VIDOVICH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700